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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2011-0525; FRL-9340-1]

α-[p-(1,1,3,3-Tetramethylbutyl)phenyl]-ω-hydroxypoly(oxyethylene); Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of α-[p-(1,1,3,3-tetramethylbutyl)phenyl]-ω-hydroxypoly(oxyethylene) (CAS Reg. Nos. 9036-19-5, 9002-93-1) when used as an inert ingredient at levels not to exceed 7% in pesticide formulations applied to growing crops and raw agricultural commodities after harvest. The Joint Inerts Task Force, Cluster Support Team Number 5 submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting establishment of an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of α-[p-(1,1,3,3-tetramethylbutyl)phenyl]-ω-hydroxypoly(oxyethylene)**.**

DATES: This regulation is effective [*insert date of publication in the* **Federal Register**]. Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the* **Federal Register**], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2011-0525. All documents in the docket are listed in the docket index available at *http://www.regulations.gov*. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

FOR FURTHER INFORMATION CONTACT: Kerry Leifer, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-8811; email address*: leifer.kerry@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

• Crop production (NAICS code 111).

• Animal production (NAICS code 112).

• Food manufacturing (NAICS code 311).

• Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl*. To access the OCSPP test guidelines referenced in this document electronically, please go to *http://www.epa.gov/ocspp* and select "Test Methods and Guidelines."

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2011-0525 in the subject line on the first page

of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before [*insert date 60 days after date of publication in the* **Federal Register**]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit a copy of your non-CBI objection or hearing request, identified by docket ID number EPA-HQ-OPP-2011-0525, by one of the following methods:

• *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the online instructions for submitting comments.

• *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

• *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305-5805.

II. Background

In the **Federal Register** of August 26, 2011 (76 FR 53372) (FRL-8884-9), EPA issued a notice pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP 1E7858) by Joint Inerts Task Force, Cluster Support Team 5, c/o CropLife America, 1156 15th St., NW., Suite 400, Washington, DC 20005. The petition requested that 40 CFR 180.910 be amended by establishing an exemption from the requirement of a tolerance for residues of α-[p-(1,1,3,3-tetramethylbutyl)phenyl]-ω-hydroxypoly(oxyethylene) (CAS Reg. Nos. 9036-19-5, 9002-93-1) when used as an inert ingredient at levels not to exceed 7% in pesticide formulations applied to growing crops and raw agricultural commodities after harvest. That notice referenced a summary of the petition prepared by Joint Inerts Task Force, Cluster Support Team 5, the petitioner, which is available in the docket, *http://www.regulations.gov*. There were no comments received in response to the notice of filing.

Previously, in the **Federal Register** of May 17, 2010 (75 FR 27443) (FRL-8826-3), EPA established a time-limited tolerance exemption for α-[p-(1,1,3,3-tetramethylbutyl)phenyl]-ω-hydroxypoly(oxyethylene) (herein referred to in this document as octylphenol ethoxylate) with an expiration date of May 17, 2012. The 2-year time limitation was established for two purposes:

1. To provide time for the development and submission of confirmatory toxicity data to address equivocal results in the available genotoxicity studies conducted on octylphenol ethoxylate (as described in Unit IV.C., of the May 17, 2010 final rule); and

2. To provide additional time, should the initial testing not confirm EPA's conclusion regarding the lack of a cancer concern, for registrants to attain EPA approval

of registration amendments for reformulation of their pesticide products to remove octylphenol ethoxylate and to replace existing products with reformulated products.

In establishing the time-limited tolerance exemption for octylphenol ethoxylate, EPA stated that if the submitted data confirmed its conclusion regarding a lack of cancer concern, the Agency intended to remove the expiration date from the tolerance exemption prior to expiration of the exemption.

III. Inert Ingredient Definition

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): Solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term "inert" is not intended to imply nontoxicity; the ingredient may or may not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

IV. Aggregate Risk Assessment and Determination of Safety

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated

dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . ."

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

Consistent with FFDCA section 408(c)(2)(A), and the factors specified in FFDCA section 408(c)(2)(B), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for octylphenol ethoxylate including exposure resulting from the exemption established by this action.

In the **Federal Register** of May 17, 2010, EPA issued a final rule establishing an exemption from the requirement of a tolerance for residues of octylphenol ethoxylate when used as an inert ingredient an inert ingredient at levels not to exceed 7% in pesticide formulations applied to growing crops and raw agricultural commodities after harvest under 40 CFR 180.910 with an expiration date of May 17, 2012. EPA has determined that establishing an exemption from the requirement of a tolerance for residues of octylphenol ethoxylate when used as an inert ingredient an inert ingredient at levels not to exceed 7% in pesticide formulations applied to growing crops and raw agricultural commodities after harvest will not significantly change the risk assessments the Agency relied on to support the May 17, 2010, tolerance action, as explained in this unit.

As part of the Agency's conduct of the risk assessment in support of the May 17, 2010, tolerance action, it was determined that there were no acute, chronic, short- or intermediate term aggregate risks of concern. With regards to aggregate cancer risk, the assessment concluded that based on a weight of the evidence consideration of the available data, the Agency believed that cancer risks would be negligible. However, due to the equivocal findings in the mutagenicity data base, the Agency asked for confirmatory data. Specifically, EPA recommended that supporters of the octylphenol ethoxylate tolerance exemption perform the following studies for confirmatory purposes:

A new Ames assay (OCSPP Harmonized Guideline 870.5100 — Bacterial reverse mutation test) and a mouse lymphoma assay (OCSPP Harmonized Guideline 870.5300 — *in vitro* Mammalian cell gene mutation test).

A bone marrow assay (OCSPP Harmonized Guideline 870.5395 — Mammalian erythrocyte micronucleus test).

Since *in vivo* mutagenicity studies such as the bone marrow assay are generally regarded as more definitive than *in vitro* studies, and a negative result in the bone marrow test may outweigh whatever results are found in the Ames test and mouse lymphoma assay, supporters of the octylphenol ethoxylate tolerance exemption were given the option of conducting the mammalian erythrocyte micronucleus test in lieu of the two *in vitro* mutagenicity studies. If those data did not confirm EPA's cancer conclusion, then EPA would need 2-year cancer bioassays in the mouse and rat (OCSPP Harmonized Guideline 870.4200 -- Carcinogenicity (mouse) and OCSPP Harmonized Guideline 870.4300 -- Combined Chronic Toxicity/Carcinogenicity (rat)) to make a safety finding in support of the tolerance exemption.

In response to the May 17, 2010, final rule, the Joint Inerts Task Force, Cluster Support Team Number 5 conducted an *in vivo* Mouse Bone Marrow Erythrocyte Micronucleus Test Following Oral Administration (OCSPP Harmonized Test Guideline 870.5395) of the representative test compound, poly(oxy-1,2-ethanediyl),α-[4-(1,1,3,3-tetramethylbutyl)phenyl]-ω-hydroxy- (CAS Reg. No. 9002-93-1). These data were submitted to the Agency on November 12, 2010 (Master Record Identification Number 48293301).

The data were evaluated by EPA and it was determined that the test substance did not induce numerical or structural chromosomal damage, providing further confirmation that octylphenol ethoxylate is not of concern for aggregate cancer risk. Further details of

this evaluation can be found at *http://www.regulations.gov* in the document "Octylphenol Ethoxylates –(JITF CST 5 Inert Ingredients).-Review of Confirmatory Mutagencity Toxicity Data" in docket ID number EPA–HQ–OPP–2011-0525.

Refer to the May 17, 2010**, Federal Register** document, available at *http://www.regulations.gov*, for a detailed discussion of the aggregate risk assessment and determination of safety.

Therefore, based on this information and the findings in the final rule published in the **Federal Register** of May 17, 2010, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to octylphenol ethoxylate residues.

V. Other Considerations

A. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nation Food and Agriculture Organization/World Health Organization food standards program, and it is

recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level. The Codex has not established a MRL for octylphenol ethoxylate.

VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established for residues of α-[p-(1,1,3,3-tetramethylbutyl)phenyl]-ω-hydroxypoly(oxyethylene) when used as an inert ingredient at levels not to exceed 7% in pesticide formulations applied to growing crops and raw agricultural commodities after harvest under 40 CFR 180.910.

VII. Statutory and Executive Order Reviews

This final rule establishes an exemption from the requirement of a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq*., nor does it require any special considerations under Executive Order 12898, entitled "Federal

Actions to Address Environmental Justice in Minority Populations and Low-Income Populations" (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq*.) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National

Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note).

VIII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq*., generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: April 26, 2012.

G. Jeffrey Herndon, Acting

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. In §180.910, the table is amended by revising the entry for the inert ingredient which reads in part "α-[p-(1,1,3,3-tetramethylbutyl)phenyl]" to read as follows:

§ 180.910 Inert ingredients used pre and post-harvest; exemptions from the requirement of a tolerance.

* * * * *

Inert Ingredients	Limits	Uses
* * * * * * *		
α-[p-(1,1,3,3-tetramethylbutyl)phenyl]-ω-hydroxypoly(oxyethylene) produced by the condensation of 1 mole of p-(1,1,3,3-tetramethylbutyl)phenol with a range of 1-14 or 30-70 moles of ethylene oxide: If a blend of products is used, the average range number of moles of ethylene oxide reacted to produce any product that is a component of the blend shall be in the range of 1-14 or 30-70 (CAS Reg. Nos. 9036-19-5, 9002-93-1)	Not to exceed 7% of pesticide formulation	Surfactants related adjuvants of surfactants
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